REMARKS

In the present response, claim 59 is amended, claims 25, 27, 35, 37, 40, and 42-45 are cancelled, and claims 60-68 are added. Therefore, claims 20, 21, and 24, 26, 28-34, 36, 38, 39, 41, 46-68 are pending with claims 20, 32, 56, and 58 being independent. Claims 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-55, 58, and 59 have been withdrawn from consideration as being directed to nonelected subject matter. Thus, at least claims 56, 57, and 60-68 should be under consideration.

Explanation, Support, and Entry of Amendment

By this amendment, Applicant amends claim 59 to change its dependency and adds new claims 60-68.

Applicant submits that each of the foregoing amendments is fully supported by the specification. New claims 60-68 correspond to claims 21 and 24-31, respectively.

Accordingly, no new matter has been added by the amendments and no estoppels are intended thereby.

Response to Election/Restriction

As noted above, claims 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-55, 58, and 59 have been withdrawn from consideration as being directed to nonelected subject matter. The Office also asserts, "Applicants are requested to amend claim 59 to cite dependence on claim 58, if this is consistent with intentions." Office Action at 2.

In response, as noted above, claim 59 has been amended to depend from claim 58. This amendment corrects an inadvertent discrepancy in the Preliminary Amendment of August 28, 2002, wherein page 6 of the Preliminary Amendment shows claim 59 depending from claim 57, and wherein the Appendix of the Preliminary Amendment shows claim 59 depending from claim 58. Applicant is happy this discrepancy is corrected.

Further, as noted in the Response to Restriction and Election of Species Requirement of October 4, 2005, Applicant traverses the Restriction and Election of Species Requirement on the grounds that the Office has not shown that there would be a serious burden to examine all of the

pending claims together. Applicant notes that the Office Action did not include a response to this argument.

Rejection under 35 U.S.C. §112, Second Paragraph

The Office has rejected claims 56 and 57 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office asserts, "Claim 56 encompasses treatment of a person who is showing no signs of osteoporosis, but for whom there is suspicion that he is vulnerable to the same." Office Action at 2. The Office then asks, "[W]hat would be the manifestations of a successful treatment for a patient who has shown no signs of osteoporosis at the time that the treatment is initiated . . . ?" Id.

In response, Applicant respectfully submits that the scope of claim 56 is clear. In this regard, claim 56 does not recite the "manifestations of a successful treatment." Claim 56 would be infringed if a mammalian host suffering from or at risk of osteoporosis were treated by administering by inhalation through the mouth of the host an aerosolized bolus of a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant. The language of claim 56 does not require "manifestations of a successful treatment." Claim 56 is clear.

In view of the above, Applicant respectfully requests that this ground of rejection be withdrawn.

Response to Rejections under 35 U.S.C. §103(a)

WANG *in view of NEER*

The Office rejects claims 56 and 57 under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,011,678 to WANG et al. ("WANG") in view of U.S. Patent No. 4,698,328 to NEER et al. ("NEER"). The Office asserts that WANG discloses that "PTH can be administered in aerosol form." Office Action at 3. The Office concedes, "Wang does not disclose fragments of PTH." Id.

The Office, however, asserts that NEER discloses "the use of PTH(1-34) and advantages associated therewith." Id. The Office then argues that it would have been obvious to "treat osteoporosis by inhaling PTH(1-34)." Id.

In response, Applicant respectfully submits that the cited documents fail to disclose or suggest a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant. Specifically, WANG teaches away from the composition of the present invention. In this regard, the invention of WANG is based on the "surprising discovery that the application of certain amphiphilic steroids described by Carey et al., supra., in the form of non-aqueous, fluorocarbon- or hydrocarbon-based aerosol suspensions is not accompanied by any significant irritation of the type experienced by many subjects upon administration of the corresponding aqueous-based delivery systems." WANG at col. 3, lines 9-17 (emphasis added). WANG states that the amphiphilic steroids of Carey et al. function as permeation enhancers that promote efficient transport of the drug across the mucosal surface. WANG at col. 1, line 64 to col. 2, line 2. In view of the amphiphilic steroid permeation enhancer, WANG teaches away from a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant.

Further support for this conclusion is found in the Examples of WANG. Example V of WANG discloses preparation of aerosol formulation for human parathyroid hormone (1-34). The preparation includes use of the following ingredients:

(1) sodium-24,25-dihydrofusidate;

(2) phosphate buffer;

(3) N-terminal 34 amino acids of parathyroid hormone;

(4) CCl_3F;

(5) CCl_2F_2.

WANG at col. 12, lines 50-64. Thus, WANG fails to disclose or suggest a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant.

NEER fails to cure the deficiencies of WANG. In this regard, NEER suggests neither administering by inhalation nor a pharmaceutical composition including an aerosol propellant. Further, NEER teaches away from the recited pharmaceutical composition. Specifically, NEER discloses a composition comprising a parathyroid hormone or physiologically active fragment thereof, or equivalents thereof, in combination with (a) a hydroxylated Vitamin D compound, or a structural or functional analogue thereof, or (b) a dietary calcium supplement. NEER at abstract. These components are described as being necessary. Id. Accordingly, the envisioned combination fails to disclose or suggest a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant.

In view of the above, Applicant respectfully requests that this ground of rejection be withdrawn.

WANG in view of MORITA

The Office rejects claims 56 and 57 under 35 U.S.C. §103(a) as allegedly being unpatentable over WANG in view of U.S. Patent No. 4,656,250 to MORITA et al. ("MORITA"). The Office asserts that MORITA discloses that "the peptide [Nle^8, $Nle1^8$, Tyr^{34}] PTH(1-34) has advantages over PTH(1-34)." Office Action at 3. The Office then argues that it would have been obvious to "treat osteoporosis by inhaling the PTH(1-34) analog that is disclosed in Morita." Id. at 4.

In response, MORITA fails to cure the above-noted deficiencies of WANG. Specifically, MORITA suggests neither administering by inhalation nor a pharmaceutical composition including an aerosol propellant. Further, MORITA fails to disclose details about pharmaceutical compositions. Accordingly, the envisioned combination fails to disclose or suggest a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant.

In view of the above, Applicants respectfully request that this ground of rejection be withdrawn.

Conclusion

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 500348.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 631-3244.

Respectfully submitted,
Nektar Therapeutics

Date: 22 May 06

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